IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

Pediamed Pharmaceuticals, Inc., Plaintiff	:	
v.	:	CIVIL NO. L-03-3443
Breckenridge Pharmaceutical, Inc., Scientific Laboratories, Inc., Defendants	:	

MEMORANDUM

Now pending are the Motions in Limine filed by Plaintiff Pediamed Pharmaceuticals, Inc. ("Pediamed"), and Defendants Breckenridge Pharmaceutical, Inc. ("Breckenridge") and Scientific Laboratories, Inc. ("SLI"). A telephonic hearing was held on December 8, 2006, which this memorandum summarizes.

For the reasons stated during the hearing, the Court DENIES the following motions:

- Breckenridge's Motion to Exclude FDA Equivalence Terms (Docket No. 141).
- Breckenridge's Motion to Exclude the Term "Knockoff" from Trial (Docket No. 142).
- Breckenridge's Motion to Exclude the Opinion Testimony of Brian C. Reisetter (Docket No. 151).

The Court DENIES Pediamed's Motion in Limine (Docket 165), except for No. 30 and No. 17. With respect to No. 30, the Court RESERVES RULING pending further argument. With respect to No. 17, because the FDA has exclusive jurisdiction to enforce the FDCA, 21 U.S.C. § 301 et seq., Breckenridge is precluded from arguing at trial:

- That Pediamed's marketing of Viravan violates the FDCA.

- That Kiel Laboratories manufactured adulterated drugs in violation of the FDCA.
- That Pediamed mislabeled Viravan in violation of the FDCA because some batches of the drug, as manufactured, had a dosage strength below the concentration stated on the label.

In these respects, the Court GRANTS request No. 17. By the same token, Pediamed is precluded from arguing at trial that Breckenridge's marketing of V-Tann violates the FDCA. Accordingly, the Court GRANTS Breckenridge's Motion to Exclude Adulteration Evidence (Docket No. 143).

The Court RESERVES RULING on the following motions, which will be taken up at a later hearing:

- Breckenridge's Motion to Exclude IMS Survey Data (No. 140).[1]
- Breckenridge's Motion to Exclude Reference to the States' Pharmacy Laws and the Legality of the Substitution of V-Tann for Viravan (Docket No. 144).
- Breckenridge's Motion to Exclude the Expert Reports of Norman Campbell, Lane Brunner, and Lamar Furr (Docket No. 145).
- Breckenridge's Motion to Exclude Opinion, Testimony, and Report of Laura B. Stamm (Docket No. 149).

During the December 8th hearing, the Court also took up the following issues:

1. Pediamed does not wish to abandon its claim against SLI. It contends that SLI may be liable under the Lanham Act by way of a "contributory responsibility" theory.[2] The Court will revisit this issue during jury instructions.

---

1 The survey's admissibility likely turns on whether Pediamed provided Breckenridge with adequate discovery concerning it.

2 See, e.g., Inwood Labs, Inc., v. Ives Labs., Inc., 456 U.S. 844 (1982); Mutual Pharm. Co. v. Ivax Pharm., Inc., -- F. Supp. 2d --, 2006 WL 302646 (C.D. Cal. Oct. 17, 2006).

2. In her summary judgment memorandum (Docket No. 125), Judge Chasanow made several rulings that were the subject of discussion and that warrant specific re-affirmation. These include her rulings:

- That Pediamed's claims are not precluded by the FDCA, which vests the FDA with exclusive jurisdiction to enforce the statute.
- That Breckenridge may not pursue an "unclean hands" defense based on Pediamed's allegedly false advertising claims regarding Viravan.
- That Pediamed violated the FDCA by failing to file a new drug application with respect to Viravan.

3. At trial, expert witnesses may testify whether certain drugs have been approved by the FDA. Because of FDCA preclusion, however, the experts may not opine whether the FDA would consider Viravan and V-Tann to be generic equivalents, or whether the FDA would or would not approve certain drugs.

4. Two factual issues must be resolved. First, whether the target audience includes not only pharmacists but also non-pharmacists involved in chain pharmacy purchasing decisions. Second, whether Pediamed must prove that members of the target audience actually relied on the alleged false advertising.

5. As Judge Chasanow found, the words "compare to" and "same active ingredients as" are open to interpretation. Both parties may offer evidence as to how the phrases are interpreted. This may include testimony from members of the target audience regarding:

- How they interpret the advertisements.
- Whether they consider the representations to be false or misleading.
- Whether the phrases have generally accepted meanings in the industry.

6. Breckenridge may offer testimony concerning the meaning that it intended to convey in its advertisements.

7. Pediamed contends that the words "compare to" and "same active ingredients as" imply that V-Tann includes the same U.S.P. grade ingredients as does Viravan. Pediamed concedes, however, that Breckenridge need not use the same manufacturing process as does Pediamed, so long as U.S.P. grade ingredients are converted into a tannate.

8. Before trial, the Court will take up whether there is an industry standard (e.g., one provided by the FDCA or "current Good Manufacturing Practices") that governs the manufacturing tolerances for prescription drugs such as these.

9. Judge Chasanow wrote that "the parties dispute what is the acceptable amount of deviation, how to calculate it, and whether the end result allows Defendants to claim that V-Tann is equivalent and therefore substitutable." The Court will take up these issues before trial.

10. The common law counts of unfair competition and tortious interference remain in the case. Pediamed has argued that under state law, punitive damages are available on a showing of malice. Under the Lanham Act, treble damages are available for compensation, but not for punishment. The Court will take up damages before trial.

Dated this 7th day of January 2007.

/s/

Benson Everett Legg
Chief Judge